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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,227	08/06/2001	Abdul Rasoul Salman	417/9-1553b	8969

7590

01/09/2003

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 01/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/923,227

Applicant(s)

SALMAN, ABDUL RASOUL

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The request for a continued examination received October 29, 2002 and Amendment B received September 25, 2002, are acknowledged. Claims 1-9 are included in the prosecution of this application.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

The term "comfortable pH" in claim 1 is a relative term, which renders the claim indefinite. The term "comfortable pH" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 2 recites glycerin as an antiseptic; the examiner is unclear how glycerin functions as an antiseptic. Further, clarification is required.

Claim 8 recites comprising and consisting language, which renders the claim indefinite. Further, it is unclear if the term mucolytic agent is defining acetylcysteine, methyl salicylate, or both.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-2 and 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hughes et al (5322689).**

Hughes et al discloses decongestant composition containing water, sodium EDTA, alcohols, glycerin, menthol, and methyl salicylate (Note examples, especially column 12).

### ***Response to Arguments***

Applicant argues that Hughes teaches a cream or ointment and it defies logic to clean the nasal passages with a greasy composition. It is argued that neither of the examples or disclosure teach spraying the composition into the nasal passage. Applicant argues that the composition contains other ingredients that change the novel property of the composition.

Applicant's arguments have been fully considered but they are not persuasive. In regards to the argument that Hughes's composition is not a cleaning composition, the examiner points out that the instant rejected claims are composition claims and the future intended use, i.e. sprayable, does not hold patentable weight.

As to the argument that Hughes composition is not in a liquid form, the examiner points out that a lotion is in a liquid form. Lastly, the examiner points out that if the prior art is capable of performing intended use, i.e. inserting it into the nasal passage, the prior art meets the claims.

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In regards to the term "consisting essentially of", the examiner points out that applicant does not clearly indicate what contained in the composition. For instance applicant merely recites "consisting essentially of" and broad categories of agents. The examiner points out that a moisturizer can be an oily substance; therefore the broad recitation of medicament categories does not limit the claim's components since many agents can perform said function. Additionally, certain agents are dually functional, i.e. methyl salicylate.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryce-Smith (5,622,724) by itself or in view of Jones et al (6,013,632).**

Bryce-Smith teaches a "zinc sulfate nasal spray for treating the common cold. The reference teaches the base solution may be saline, aqueous glycerol, or a mixture of both (col. 5, lines 6-14). Further, Bryce-Smith teaches a preferred solution containing zinc, ethanol, camphor, and menthol. Lastly, Bryce-Smith suggests combining the zinc solution with other medications such as decongestants, antimicrobials, or antihistamines (col. 5, lines 28-45).

Bryce-Smith does not exemplify the solution.

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Although the reference does not exemplify the zinc solution, it is deemed obvious to one of ordinary skill in the art at the time the invention was made to provide for such a zinc nasal solution since Bryce-Smith teaches it as a preferred embodiment.

Bryce-Smith does not specify the use of N-acetylcysteine.

Jones et al teach N-acetylcysteine nasal spray for the prevention or treatment of infection by the influenza virus (example 24). Jones teaches the N-acetylcysteine is a common mucolytic agent (col. 2, lines 10-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use N-acetylcysteine in Bryce-Smith's nasal spray since Jones teaches the common use of N-acetylcysteine as a mucolytic agent. One would be motivated to do so with a reasonable expectation of success since Bryce-Smith suggests the inclusion of other medicaments such as decongestants in the zinc composition.

**Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryce-Smith (6,013,632) in view of Pan et al (5,912,007).**

As set forth above, Bryce-Smith teaches a zinc nasal spray. Further, the reference teaches using the spray to clear the nasal congestion.

Bryce-Smith does not specify N-acetylcysteine or methyl salicylate.

Pan et al teach a medicated composition for the upper respiratory tract. Pan teaches the use of methyl salicylate as a topical antimicrobial and N-acetylcysteine as an expectorant agent (col. 3, lines 40-45 and lines 61-63).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to use N-acetylcysteine and methyl salicylate in Bryce-Smith's zinc composition since Pan teaches N-acetylcysteine as an expectorant agent and methyl salicylate as an antimicrobial agent. One would be motivated to do so with a reasonable expectation of success since Bryce-Smith the inclusion of other medicaments such as decongestants and antimicrobials in the composition.

### ***Response to Arguments***

Applicant's arguments with have been considered but are moot in view of the new ground(s) of rejection. However, in the advancement of compact prosecution the examiner provides the reason for the use of Pan et al.

Applicant argues that Pan is related to medicaments of the upper respiratory tract, i.e. the oral pharyngeal area, and administration via solid dosage forms. Therefore, one would not look to Pan et al for a nasal composition.

The examiner points out that the secondary reference is relied upon only for its specific teachings of the instant compounds. Pan teaches the use of pharmaceuticals that are compatible with the upper respiratory tract. The examiner points to column 11 and 12 in which Pan teaches the effects of the composition on the nasal passages. Further, the examiner points out that the upper respiratory includes the nasopharyngeal area, therefore one of ordinary skill in the art would expect similar results. Lastly, it is the examiner's position that it is within the skill of the art to include medicaments in the desired form (solid versus liquid) unless the applicant can provide evidence of the instant active agent changing its properties in a given form. Additionally, the examiner

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points to column 7, lines 43-54 where Pan teaches the suitable carrier can be in the form of a suspension or syrup. Clearly, the instant compounds may be incorporated into a liquid form.


### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 703-305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 709-3080196.

SSG

  
January 6, 2003

  
MICHAEL G. HARTLEY  
PRIMARY EXAMINER